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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,190	04/10/2001	Katsuya Matsuda	MATSUDA 13	4190

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EXAMINER
GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 09/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/807,190	MATSUDA ET AL.	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-32, 35-39, 42-, 44, 46-49, and 53-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31-32, 35-39, 42-, 44, 46-49, and 53-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Request for Continued Examination and Amendments/Remarks filed 7/17/06 is acknowledged. Claims **31-32, 35-39, 42-, 44, 46-49, and 53-59** are pending in this application. Claims 1-30, 33-34, 40-41, 45, and 50-52 stand cancelled.

Response to Arguments

Applicant's arguments filed 7/17/06 have been fully considered but they are not persuasive.

Applicant argues that Holmes-Farley does not teach the use of microcrystalline cellulose (hereinafter referred to as MCC) in a tablet and the inherent stickiness of the phosphate-binding polymers. Applicant argues there is only a fleeting reference to tablets in Holmes-Farley. It is argued that the use of at least 10% MCC and low substituted hydroxypropylcellulose (hereinafter referred to as l-HPC) provides a tablet that is less sticky and easily swallowed. Applicant argues that the Declaration of 2/16/05 demonstrates that it is difficult or impossible to predict whether excipients will be appropriate to reduce stickiness of the phosphate-binding polymers.

Firstly, the examiner points out that although Holmes-Farley does not exemplify a tablet formulation, Holmes-Farley *suggests* formulating the phosphate-binding polymers as a tablet. It is pointed out a reference need not exemplify all embodiments to suggest or anticipate an invention. Although Holmes-Farley exemplifies a capsule, disclosed examples and preferred embodiments do not constitute a teaching away form the broader disclosure or nonpreferred embodiment". In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971).

Secondly, it is the examiner's position that Holmes-Farley also suggests the use of conventional excipients including microcrystalline cellulose since US '754 incorporates the

disclosure of US 5,496,545 and 5,487,888. US '545 on column 17, lines 40-46 teaches the use of microcrystalline cellulose as a suitable carrier. It should be noted that when a reference is incorporated by reference, the information incorporated is as much a part of the application as filed as if the text was repeated in the application, and should be treated as part of the text of the application as filed. See MPEP 2163.07(b). The only teaching lacking in the references is the weight percent of microcrystalline cellulose. However, Yaginuma et al cure this deficiency. The examiner points out that the motivation to combine two references need not be the same as the applicant's. In response to applicant's argument that applicant has found out that MCC reduces stickiness, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

With regard to the Rule 132 Declaration, the declaration is found not to be persuasive for the following reasons: firstly, the examiner notes that the "unexpected results" of reducing stickiness are based on the use of 33.3% MCC. Thus, the claims are not commensurate in scope with the unexpected results. Secondly, the examiner points out that the declaration is not based on a comparison of the closest prior art. For instance, applicant compared MCC with HPMC and HPC; however US '754 (incorporating US '545) and US '545 teach the suitability of lactose, dextrose, sucrose, sorbitol, mannitol, starches, gum acacia, alginates, tragacanth, gelatin, calcium silicate, microcrystalline cellulose, polyvinylpyrrolidone, cellulose, methylcellulose, methylhydroxybenzoates, propylhydroxybenzoates, propylhydroxybenzoates, and talc. Thus, applicant should provide results comparing one of these excipients with MCC/l-HPC. Thirdly,

the examiner points out that the prior art actually teaches applicant's "unexpected result of reducing stickiness" utilizing microcrystalline cellulose.

The examiner points out that this is a known feature of MCC. US 3,146,168 cited as art of interest discloses that microcrystalline cellulose has superior compressibility, cohesive strength, and **is less tacky and sticky**. See column 5, lines 6-10 and 35-74. JP 359049840 discloses the use of MCC to prevent sticking. See abstract. US 5,589,438 discloses:

> Optionally, to further improve flowability, reduce sticking tendency or caking, or to increase the dissolution rate, binders, fillers, and/or disintegrants can be dissolved in the feed solution before drying. Suitable binders, fillers, and/or disintegrants include water-soluble cellulose derivatives, cellulose derivatives, carboxymethyl cellulose, hydroxypropyl methylcellulose, water soluble gums such as gum arabic, gum tragacanth, alginates, gelatin, and polyvinylpyrollidone, cross-linked polyvinylpyrollidone, microcrystalline cellulose, modified starches such as sodium carboxymethyl starch, and mixtures thereof.

Thus, the Rule 132 declaration is considered to be unpersuasive.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 31-32, 35-39, 42-, 44, 46-49, and 53-59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claim 31 and 39 have been amended to recite "crystalline cellular" which is vague and indefinite since it is unclear what the term "crystalline *cellular*" is and the specification does not define it. Further, the term "crystalline *cellular*" also lacks antecedent basis. It appears applicant is intending to limit the weight percent of crystalline *cellulose* and "cellular" is a typographical error; therefore the examiner not rejecting the term under new matter. However, if the claim is not amended to remove the word "cellular" and applicant

intends to claim "crystalline cellular", then the claim will be rejected under new matter and the examiner retains the right to go final.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 31-32, 36, 39, 42-44, 49, 53-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holmes-Farley et al (6,423,754) in view of Holmes-Farley et al (5,496,545) in further view of in view of Yaginuma et al (5,574,150).

Holmes-Farley et al disclose the method of preparing cross-linked phosphate-binding polymers in oral formulations for the treatment of hypercholesterolemia and hyperphsophatemia. See abstract and column 3, lines 35-50. The polymers are prepared by combining polyallylamine hydrochloride, acetonitrile, water, and epichlorohydrin, yielding particles in a solution. The solid particles are then dried and passed thorough a 50-mesh screen (approximately 300 microns). See examples on column 6, lines 15-45. Suitable forms for administration are tablets, capsules, or

powders. The polymer may be administered alone or in combination with a carrier such as magnesium carbonate, lactose, or a phospholipid with which the polymer can form a micelle and can be coated to protect the composition from disintegration. See column 3, lines 35-60. Further, the disclosure of US 5,496,545 and 5,487,888 are incorporated by reference.

It should be noted that although the prior art does not teach the instant specific gravity and properties, it is the examiner's position that these are inherent in Holmes-Farley since applicant discloses the instant phosphate-binding polymers have the instant specific gravity due to the specific preparation utilizing a solvent mixture of water and acetonitrile and crosslinking polyallyamine with epichlorohydrin, which is the same solvent mixture utilized by the prior art to prepare the phosphate-binding polymer particles. Further, the submitted declaration of 3/10/05 demonstrates that the instant polymers by themselves have a hardness of 6.2 KP.

Holmes-Farley et al does not exemplify the tablet formulation or teaches at least 10% of crystalline cellulose or l-HPC.

Holmes-Farley (US '545) teaches phosphate-binding polymers for oral administration. See abstract. US '545 teaches the pharmaceutical compositions are ***prepared by known procedures using well-known and readily available ingredients***. In making the compositions, the polymeric phosphate binder may be present alone, or may be admixed with a carrier, diluted by a carrier, or enclosed within a carrier. The compositions can be in the form of tablets, pills, powders, lozenges, sachets, cachets, elixirs, suspensions, syrups, aerosols, (as a solid or in a liquid medium), soft or hard gelatin capsules, sterile packaged powders, and the like. Examples of suitable carriers, excipients, and diluents include lactose, dextrose, sucrose, sorbitol, mannitol, starches, gum acacia, alginates, tragacanth, gelatin, calcium silicate, microcrystalline cellulose,

polyvinylpyrrolidone, cellulose, methylcellulose, methylhydroxybenzoates, propylhydroxybenzoates, propylhydroxybenzoates, and talc. See column 17, lines 40-46.

Yaginuma et al disclose improved microcrystalline cellulose with high compactability. Yaginuma discloses the *conventional and wide use* of microcrystalline cellulose in the art since it exhibits high safety, a relatively high compactability and a relatively excellent rate of disintegration. Further, Yaginuma teaches the prior art disclosing the use of microcrystalline cellulose to increase strength of tablets. See column 1, lines 16-40. However, Yaginuma teaches the prior art's microcrystalline cellulose have disadvantages in that when the compactability is high, the rate of disintegration is lowered and when the rate of disintegration is high, the compactability is low. However, Yaginuma teaches an improved microcrystalline cellulose with both high compactability and disintegration. See column 3, lines 30-37. Further, the reference teaches the inventive microcrystalline cellulose may be used in a limited amount to make a small tablet and yet provide the same properties. See column 15, lines 25-32. Yaginuma teaches tablets require at least 4 kgf (4kp) breaking strength and the inventive microcrystalline cellulose provides a strength of 10 kgf (10kp) or mere. See column 15, line 40 to column 14, lines 15.The examples teach combining inventive microcrystalline cellulose (19%) with an active, and lactose and compressing the mixture.

Firstly, it would have been obvious to one of ordinary skill in the art at the time the invention was made combine the teachings of US '754 and US'545 and utilize microcrystalline cellulose as the excipient of choice when formulating a dosage form. One would have been motivated to do so since US '545 teaches an oral dosage form comprising phosphate binding polymers wherein the conventional excipient may be microcrystalline cellulose. A skilled artisan

would have reasonably expected success and similar results since US '754 teaches the use of any conventional excipient in formulating the dosage forms containing the phosphate-binding polymer and incorporates the teachings of US '545. Thus, the suggestion to utilize microcrystalline cellulose is in US '754 itself.

Secondly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teaching of Holmes-Farley (US '754 and US '545) and Yaginuma and specifically select instant microcrystalline cellulose as the excipient of choice and utilize it is the instant amount. One would have been motivated to do so since Yaginuma teaches the state of the art wherein it is known and conventional to use microcrystalline cellulose to increase the strength of a tablet. Moreover, Yaginuma teaches an improved microcrystalline cellulose that not only improves strength to yield a tablet having a hardness of 10 KP but also good disintegration. Therefore, if a skilled artisan desired to increase the strength of tablet, it would have been prima facie to utilize microcrystalline cellulose as the excipient of choice. Furthermore, it is the examiner's position that the selection of a conventional and routinely utilized excipient is prima facie obvious especially since Homes-Farley suggests the use of microcrystalline cellulose.

With regard to the limitations of claims 54-59, it is the examiner's position that since the prior art teaches the same phosphate binder and the same excipient (microcrystalline cellulose) the weight loss would be the same absent evidence to the contrary.

Claims 31-32, 36, 38-39, 42-44, 48-49, 53-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holmes-Farley et al (6,423,754) in view of Holmes-Farley et al (5,496,545) in further view of Takeo et al (4,159,345).

Holmes-Farley et al disclose the method of preparing cross-linked phosphate-binding polymers in oral formulations for the treatment of hypercholesterolemia and hyperphsophatemia. See abstract and column 3, lines 35-50. The polymers are prepared by combining polyallylamine hydrochloride, acetonitrile, water, and epichlorohydrin, yielding particles in a solution. The solid particles are then dried and passed thorough a 50-mesh screen (approximately 300 microns). See examples on column 6, lines 15-45. Suitable forms for administration are tablets, capsules, or powders. The polymer may be administered alone or in combination with a carrier such as magnesium carbonate, lactose, or a phospholipid with which the polymer can form a micelle and can be coated to protect the composition from disintegration. See column 3, lines 35-60. Further, the disclosure of US 5,496,545 and 5,487,888 are incorporated by reference.

It should be noted that although the prior art does not teach the instant specific gravity and properties, it is the examiner's position that these are inherent in Holmes-Farley since applicant discloses the instant phosphate-binding polymers have the instant specific gravity due to the specific preparation utilizing a solvent mixture of water and acetonitrile and crosslinking polyallyamine with epichlorohydrin, which is the same solvent mixture utilized by the prior art to prepare the phosphate-binding polymer particles. Further, the submitted declaration of 3/10/05 demonstrates that the instant polymers by themselves have a hardness of 6.2 KP.

Holmes-Farley et al does not exemplify the tablet formulation or teaches at least 10% of crystalline cellulose or l-HPC.

Holmes-Farley (US '545) teaches phosphate-binding polymers for oral administration. See abstract. US '545 teaches the pharmaceutical compositions are ***prepared by known procedures using well-known and readily available ingredients***. In making the compositions, the polymeric phosphate binder may be present alone, or may be admixed with a carrier, diluted by a carrier, or enclosed within a carrier. The compositions can be in the form of tablets, pills, powders, lozenges, sachets, cachets, elixirs, suspensions, syrups, aerosols, (as a solid or in a liquid medium), soft or hard gelatin capsules, sterile packaged powders, and the like. Examples of suitable carriers, excipients, and diluents include lactose, dextrose, sucrose, sorbitol, mannitol, starches, gum acacia, alginates, tragacanth, gelatin, calcium silicate, microcrystalline cellulose, polyvinylpyrrolidone, cellulose, methylcellulose, methylhydroxybenzoates, propylhydroxybenzoates, propylhydroxybenzoates, and talc. See column 17, lines 40-46.

Takeo et al teaches an excipient (microcrystalline cellulose) for use in manufacture of tablets, capsules, powders, microgranules and granules. The pharmaceutical composition comprises a pharmaceutically active ingredient and the excipient. The excipient has improved flowability and moldability or compressibility and pharmaceutical compositions obtained using the excipient are excellent in various pharmaceutical characteristics such as rate of disintegration, rate of dissolution, etc. see abstract. Takeo teaches conventional solid pharmaceutical compositions generally comprise (i) a main ingredient (pharmaceutically active ingredient), (ii) an excipient, (iii) a binder, (iv) a disintegrating agent and (v) other additives. See column 1, lines 45-50. Takeo teaches preparing tablets via direct compression method comprises a main ingredient, an excipient, a binder, and a disintegrating agent. Takeo teaches when the flowability of the main ingredient is extremely poor, if the concentration of the main ingredient

exceeds a certain level, the flowability of the powdery mix is drastically reduced, and direct compression becomes difficult or the weight of the main ingredient content becomes extremely uneven in the resulting tablets. Takeo teaches that if microcrystalline cellulose is used in an amount of lower than 15% by weight based on the composition, then an uneven tablet is produced due to poor flowability. Further, if the content of microcrystalline cellulose is lower than 10% by weight based on the composition, the practical strength of resulting tablets is not increased and the disintegration time of the tablets is long. Thus, Takeo teaches microcrystalline cellulose should be incorporated in an amount of at least 10% by weight based on the composition. See column 7-8. Takeo teaches film- or sugar-coating the tablets as conventionally done in the art. See column 8, lines 58-65. Takeo teaches the method of making the tablet with MCC, lactose, and magnesium stearate (lubricant). Takeo teaches the MCC provides a hardness of 9.8. See Table 17.

Firstly, it would have been obvious to one of ordinary skill in the art at the time the invention was made combine the teachings of US '754 and US'545 and utilize microcrystalline cellulose as the excipient of choice when formulating a dosage form. One would have been motivated to do so since US '545 teaches an oral dosage form comprising phosphate binding polymers wherein the conventional excipient may be microcrystalline cellulose. A skilled artisan would have reasonably expected success and similar results since US '754 teaches the use of any conventional excipient in formulating the dosage forms containing the phosphate-binding polymer and incorporates the teachings of US '545. Thus, the suggestion to utilize microcrystalline cellulose is in US '754 itself.

Secondly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teaching of Holmes-Farley (US '754 and US '545) and Takeo and specifically select instant microcrystalline cellulose as the excipient of choice and utilize it is the instant amount. One would have been motivated to do so since Takeo teaches the advantages of microcrystalline cellulose as set forth above, such as to increase the strength of a tablet without impairing disintegration time, MCC improves processing since MCC has improved flowability, compressibility etc.. Therefore, if a skilled artisan desired to increase the strength of tablet, it would have been prima facie to utilize microcrystalline cellulose as the excipient of choice. Furthermore, it is the examiner's position that the selection of a conventional and routinely utilized excipient is prima facie obvious especially since Homes-Farley suggests the use of microcrystalline cellulose.

With regard to the limitations of claims 54-59, it is the examiner's position that since the prior art teaches the same phosphate binder and the same excipient (microcrystalline cellulose) the weight loss would be the same absent evidence to the contrary.

Claims 35 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holmes-Farley et al (6,423,754) in view of Holmes-Farley et al (5,496,545) in view of in view of Takeo et al (4,159,345) in further view of Kitanishi (4971805).

The teachings of Holmes-Farley and Takeo have been delineated above. Takeo teaches the conventional solid pharmaceutical compositions generally comprise (i) a main ingredient (pharmaceutically active ingredient), (ii) an excipient, (iii) a binder, (iv) a disintegrating agent and (v) other additives and Takeo teaches MCC may be combined with a disintegrating agent.

The references, in particular Takeo, do not specify the disintegrating agent or teach instant L-HPC.

Kitanishi teaches low-substitution hydroxypropyl cellulose (manufactured by Shin-Etsu Chemical Company with about 5 to 16% by weight of hydroxypropyl groups content, and abbreviated to L-HPC) is a "powerful" disintegrating agent to increase the rate of dissolution and the agent is used in an amount of 1-10%. See column 4, lines 35-60.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of the above references and further utilize L-HPC as the disintegrating agent. One would have been motivated to do so with the expectation of success since Kitanishi teaches L-HPC is a good disintegrating agent and Takeo teaches the use of MCC and a disintegrating agent. Therefore, a skilled artisan would have been motivated to utilize a disintegrating such as L-HPC to provide for a tablet that quickly dissolved.

Claims 37 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holmes-Farley et al (6,423,754) in view of Holmes-Farley et al (5,496,545) in view of in view of Takeo et al (4,159,345) in further view of Kitanishi (4971805) in further view of Nakajima (3926817).

The teachings of Holmes-Farley, Takeo, and Kitanishi have been set forth above. Takeo teaches the conventional solid pharmaceutical compositions generally comprise (i) a main ingredient (pharmaceutically active ingredient), (ii) an excipient, (iii) a binder, (iv) a disintegrating agent and (v) other additives and Takeo teaches magnesium stearate as a conventional lubricant.

The references do not teach the instant lubricant: hardened oil.

Nakajima teaches stearic acid, magnesium stearate, and hydrogenated castor oil have been widely employed in various pharmaceutical preparations. See column 2, lines 50-55.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the above references and utilize the instant hydrogenated oil in place of Takeo's magnesium stearate. One would have been motivated to do so since Nakajima teaches the instant lubricant and the prior art's magnesium stearate are both utilized as glidants in pharmaceutical compositions. Therefore, it is prima facie obvious to substitute one functional equivalent for another functionally equivalent agent with the expectation of success.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 31-32, and 35-38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 6,383,518 and 6,696,087. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are directed to similar subject matter.

The instant application is directed to a tablet having a hardness of 6KP and comprising phosphate-binding polymers with particle size of no larger than 500 microns and at least one of

crystalline cellulose and l-HPC. The particles have a moisture content of 1-14%. Claim 37 is directed to the use of a hardened oil. Claim 38 is to the tablet having a water-soluble coating.

US '518 is directed to a tablet comprising a phosphate binding polymer having a specific formula and having a particle size of 500 microns or less, and crystalline cellulose and/or l-HPC. Claim 2 is directed to a tablet that comprises phosphate-binding polymers with a moisture content of 1-14% and crystalline cellulose and/or l-HPC. Dependent claims are directed to the use of a hardened oil. Dependent claims are directed to a tablet having water-soluble coating.

US '087 is directed to a tablet with a hardness of 6KP or more comprising phosphate-binding polymers having a specific formula and crystalline cellulose and/or l-HPC. Dependent claims are directed to the use of a hardened oil. Dependent claims are directed to a tablet having water-soluble coating.

The instant application, which does not specify the formula of the phosphate-binding polymer, is directed to the broader scope of US patents '518 and '087. Thus, the instant application fully encompasses the subject matter of the patented claims.

Response to Arguments

Applicant has not argued the merits of this rejection. Therefore, the rejection is maintained.

Conclusion

None of the claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sharmila S. Gollamudi
Examiner
Art Unit 1616